

510(k) Summary

MAY - 2 2005

K 650872

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7688
Contact Person: Dimitris Demirtzoglou
Date Prepared: April 1, 2005

2) Device name

Proprietary name: Accu-Chek Integra System
Classification name: Glucose dehydrogenase, glucose test system
(21 C.F.R. § 862.1345)(75LFR)

3) Predicate device

We claim substantial equivalence to the current legally marketed Accu-Chek Compact System (K#031755).

4) Device Description

Instrument Operating Principle -- photometry
Reagent Test Principle -- glucose dehydrogenase

5) Intended use

The Accu-Chek Integra system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale.

Professionals may use the test strips to test capillary and venous blood samples; lay use is limited to capillary whole blood testing. Capillary blood samples can be acquired from fingertips, forearm, upper arm, thigh, calf and palm.

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- 6) Similarities** The Roche Diagnostics Accu-Chek Integra System is substantially equivalent to the current legally marketed Accu-Chek Compact (predicate) System. The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The Accu-Chek Integra and Accu-Chek Compact systems are designed to quantitatively measure the concentration of glucose in capillary whole blood for monitoring glucose. The devices are indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary and venous blood samples; lay use is limited to capillary whole blood testing. Both systems are indicated for Alternate Site Testing use.
Test principle	Glucose dye oxidoreductase mediator reaction.
Test strip storage conditions	Store at room temperature between +36° F (+2° C) and +86° F (+30° C).
Test strip operating conditions	Between +5° F (+10° C) and +104° F (+40° C).
Quality control testing frequency	Tests should be run with liquid quality control materials whenever a new vial of test strips is opened or an unusual blood test result is obtained.
Quality control acceptable range	The mean is strip lot specific and will be determined individually. The range of the controls is within ± 15 mg/dL or $\pm 15\%$ compared to the determined mean.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 65–95 mg/dL (related to whole blood) mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for the patients.
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC recovery range contact Roche Diagnostics's Accu-Chek Customer Care center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.

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6) Similarities (continued)

Feature/Claim	Detail
Acceptable sample types	Capillary whole blood samples from a fingerstick or AST site. Venous blood may also be used only if drawn by health care professionals.
Reportable range	10-600 mg/dL
Hematocrit range	25 - 65%
Warnings and precautions	For <i>in vitro</i> diagnostic use only.

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**7) Data
demonstrating
substantial
equivalence**

Performance testing on the modified Accu-Chek Integra System demonstrated that the device meets the performance requirements for its intended use. A multi-center performance study was conducted to evaluate the accuracy and precision of the modified device. The clinical data demonstrates that the performance of the Accu-Chek Integra correlates well with the laboratory plasma glucose reference test method. All predetermined acceptance criteria were satisfied. The data also demonstrates that the Accu-Chek Integra is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY - 2 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
PO Box 50416
Indianapolis, IN 46250

Re: k050872
Trade/Device Name: Accu-Chek Integra Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR, NBW
Dated: April 4, 2005
Received: April 6, 2005

Dear Mr. Demirtzoglou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

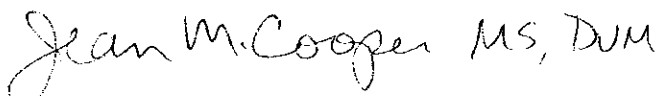
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink that reads "Jean M. Cooper MS, DVM". The signature is written in a cursive style with a large, stylized "J" and "C".

Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Accu-Chek Integra Test System

Indications For Use:

The Accu-Chek Integra system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals for monitoring glucose in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale.

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Prescription Use X
(Part 21 CFR 801 Subpart D)

 AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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